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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/076,115	05/12/1998	CHRISTIAN E. GRUBER	0942.4350001	4470
26111	7590	05/28/2004	EXAMINER	
STERNE, KESSLER, GOLDSTEIN & FOX PLLC 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005			TUNG, JOYCE	
			ART UNIT	PAPER NUMBER
			1637	

DATE MAILED: 05/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	09/076,115		GRUBER ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Joyce Tung		1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 64-68, 70-89 and 91-135 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 64-68, 70-89 and 91-135 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>2/28/2003</u> | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

The applicant's response filed March 26, 2004 to the Office action has been entered.

Claims 64-68, 70-89, and 91-135 are pending.

1. Claims 64-68, 70-89, and 91-122 remain rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Spinella et al. (5,968,784, issued 10/19/1999).

The response argues that the method of Spinella et al. involves cleavage using at least two enzymes to cleave cDNA molecules and the reference clearly discloses that the cDNA molecule is not cleaved within the primer adapter. However, although the method of Spinella et al. applies two enzymes to cleave cDNA, one of the enzymes cleaves the cDNA, which is within the primer adapter (See column 7, lines 9-13 and fig. 2). Thus, the teachings of Spinella anticipate the limitations of the claims.

The response further argues the rejection under 35 U.S.C. 103(a) in that there is no motivation to modify the method of Spinella et al. to reach the methods presently claimed, because such modification would render Spinella unfit for its intended purpose. However, claim language does not indicate the intended use of the produced cDNA molecule of the instant claims. Since the method of Spinella et al. is very useful for identifying gene expression (See the Abstract), the cDNA preparation is a part of the method, which would be very critical. Therefore, one of ordinary skill in the art would have been motivated to use the method of Spinella et al. to make cDNA. Thus Applicant's arguments filed March 26, 2004 have been fully considered but they are not persuasive. The rejection is maintained.

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The newly added claims 123-135 are also rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Spinella et al. (5,968,784, issued 10/19/1999) because Spinella et al. teach transcriptase MMLV-H-RT (See column 16, lines 49-52 and lines 62-65) and the ligand, streptavidin (See fig. 2).

## **NEW GROUNDS OF REJECTION NECSITATED BY THE AMENDMENT**

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 124, 127, 129, 132 and 135 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spinella et al. (5,968,784, issued 10/19/1999) as applied to claims 64-68, 70-89, and 91-135 above, and further in view of Ando et al. (Journal of Clinical Microbiology, March 1997, Vol. 35(3), pg. 570-577).

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The teachings of Spinella et al. are set forth in section 3 of the Office action mailed 10/6/2003. Spinella et al. do not disclose using SuperScript reverse transcriptase in the method.

Ando et al. disclose a one tube- RT-PCR method that permits routine amplification of the 3-kb region of genetically distinct SRSV strands present in low concentrations in stool samples (See pg. 570, column 2, second paragraph). The key element of the method is that first strand cDNA is synthesized with SuperScript II version of Rnase H<sup>-</sup> Moloney murine leukemia virus reverse transcriptase (See the Abstract).

One of ordinary skill in the art would have been motivated to modify the method of Spinella et al. by applying reverse transcriptase, SuperScript because Ando et al. disclose the method which uses reverse transcriptase, SuperScript permits routine amplification of the 3-kb region of genetically distinct SRSV strands present in low concentrations in stool samples (See pg. 570, column 2, second paragraph). It would have been prima facie obvious to use reverse transcriptase, SuperScript for making cDNA molecule.

#### Summary

4. No claims are allowable
5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

7. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

May 21, 2004



KENNETH R. HORLICK, PH.D  
PRIMARY EXAMINER

5/25/04